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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Denise Belsham

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CANADA

EXAMINER

GUCKER, STEPHEN

ART UNIT

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,591	Applicant(s) BELSHAM ET AL.	
	Examiner STEPHEN GUCKER	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7-13 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/2/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group IV, claims 1-2, 6, and 14 in the reply filed on 10/10/08 is acknowledged. The traversal is on the ground(s) that a greater burden would be placed on the applicant to prosecute each group as defined by the Examiner separately, than would be placed on the USPTO given the overlapping class and subclasses listed on the restriction requirement. This is not found persuasive because the separate inventions of the instant application lack unity of invention for reasons of record and present a search burden; see pages 8-9 of the office action filed 4/10/08. The burden on applicant to prosecute each group is immaterial to the traversal.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-5, 7-13, and 15-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/10/08.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Because of the restriction requirement filed 4/10/08, claim 6 is no longer further limiting the scope of claim 1. Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen et al. (abstract only, Endocrinology 1990; “Rasmussen”) in light of Frago et al. (“Frago”). Rasmussen discloses an SV40 transformed fetal rat hypothalamic cell line called RCA-6. SV40 is a virus that encodes large T antigen and immortalizes cell lines (as disclosed in the working examples of the instant application) and is a species of the genus of polyoma virus as recited in the claims (see the specification on page 11, lines 24-28, and the definition from Stedman's Medical Dictionary, 27th ed., 2000). Frago is used solely to exemplify the inherent characteristics of the RCA-6 cell line which was disclosed in the 1990 abstract. Figure 3B of Frago demonstrates that the RCA-6 cell line is inherently immunopositive for neuropeptide Y (NPY). Further evidence that RCA-6 cells inherently express NPY is found in Table 2 of Frago, wherein it is disclosed that the mRNA for NPY was detected.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

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later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2, 6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magni et al. ("Magni") in view of Rajakumar et al. ("Rajakumar"), further in view of Eves ("Eves"), and further in view of Beck et al. (abstract only, "Beck"). Magni teaches that NPY has been implicated in the regulation of several important brain functions such as induction of feeding behavior (page 976). Magni discloses mixed cell population cultures of murine hypothalamic embryonic brain cells expressing NPY (pages 977-978 and 982). Magni does not teach immortalizing his cell cultures in order to produce immortalized cell lines. Rajakumar also teaches that NPY mediates several different biological functions, including hyperphagia leading to obesity (page 123), i.e. overeating. Rajakumar discloses several cell lines of murine embryonic hippocampal neuronal cells expressing NPY (abstract) which were immortalized by being transformed by simian virus 40 (SV40) large tumor (T) antigen by Eves (see page 124 of Rajakumar, under "2.1 Cell lines", where Eves is referenced ("[14]")) as the source of the cell lines used). Eves is used to exemplify that the cell lines used by Rajakumar were immortalized by being transformed by simian virus 40 (SV40) large tumor (T) antigen by retroviral infection (see page 4373 of Eves). Eves also teaches bilaminar mixed cell cultures, isolating transfected cells from non-transfected cells, subcloning, screening for neuronal markers, and further cloning (pages 4373-4377). Beck teaches that hyperphagia and obesity are often associated, food intake is regulated by numerous peptides in the hypothalamus, NPY is the most potent neuropeptide inducer of food intake in the hypothalamus, and that in the hyperphagic obese Zucker rat, hypothalamic NPY concentrations are significantly greater than

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those in the lean normophagic rats (abstract). It would have been obvious for one of ordinary skill in the art at the time of the invention to modify the murine hypothalamic NPY-expressing cell cultures of Magni by transforming Magni's cultures with the SV40 large T antigen as taught by Rajakumar and Eves in order to produce immortalized hypothalamic neuronal cell lines expressing NPY because of the nexus of recognition by Magni, Rajakumar, and Beck that NPY is important in regulating feeding behavior and that excess NPY concentrations in the hypothalamus is an underlying cause of obesity as suggested by Beck. Motivation to produce immortalized neuronal cell lines is provided by Eves: "Although primary culture techniques can enrich for particular cell types of interest, they do not easily produce sufficient material for biochemical analysis. An alternative approach, the use of tumor cell lines with neural phenotypes, is limited by their malignant nature and lack of cell-lineage specificity. For these reasons, it would be advantageous to have available cell lines of known brain-region origin that express phenotypes of particular subsets of cells" (page 4373). Additional motivation to produce immortalized cell lines specifically expressing NPY is provided by Rajakumar: "In order to sort through NPY gene regulation mechanistically, it is vital to develop a neural cell line which mimics the embryonic rat brain with respect to NPY synthesis" (pages 123-124).

9. No claim is allowed.

10. This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

February 9, 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. The examiner has not been able to find a copy of applicant's own prior art that is disclosed in the application, namely "Shkreta L, Belsham DD 2000 Establishment of immortalized hypothalamic neuronal cell lines expressing specific neuropeptide genes. *Endocrine Society Annual Meeting* 82: 284" (page 47, lines 27-29). The examiner believes that this was the Endocrine Society's 82nd annual meeting which took place in Toronto, Canada in the year 2000, but the examiner has not been able to locate any publications which might list the abstracts or summaries of any poster sessions or other public presentations that occurred at this meeting, and the applicant may be able to provide a copy since it is her own work.

In response to this requirement, please provide copies of each publication/public presentation (lecture, seminar, etc.) which any of the applicants authored or co-authored and which describe the disclosed subject matter of immortalized hypothalamic neuronal cell lines that took place during the Endocrine Society's Annual Meeting of 2000.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily

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obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

February 9, 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649